NRC INSPECTION MANUAL

PART 9900: 10 CFR GUIDANCE

50B R.CFR

10 CFR 50, APPENDIX B

RESPONSIBILITY - REVIEW AND APPROVAL OF LICENSEE QA PLANS FOR OPERATION

A. PURPOSE

The purpose of this guidance is to clarify the status of licensee QA plans for operation and to identify the NRC organizations that have responsibility for reviewing the various segments of such QA plans.

B. BACKGROUND

The term QA plan is normally used to describe the overall QA package that must be prepared by a licensee to satisfy the requirements of 10 CFR 50, Appendix B, Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants. This term is subdivided into (1) the QA Program description (Docketed Program) that is submitted to NRR for review and approval and (2) specific procedures, normally called the QA Manual(s), that describe how the licensee will implement the commitments in the NRR approved QA Program for operation. The licensee has the option of describing the proposed QA Program in the Facility Safety Analysis Report or in a Topical Report. From a QAB/NRR standpoint, the review of both documents is essentially the same.

C. STATUS - QA PROGRAMS FOR OLDER FACILITIES (LICENSED PRIOR TO 1973/74)

QA Programs for operation that were approved for older facilities, licensed prior to 1973/74, are slightly different than the QA Programs that were approved after that time period. These differences result from the fact that the facilities had been licensed prior to the imposition of the requirements of 10 CFR 50, Appendix B. At that time NRC management made a decision that the older facilities would have to comply with QA Program requirements delineated in the Rainbow Books, i.e., WASH 1284, Guidance on Quality Assurance Requirements During the Operations Phase of Nuclear Power Plants, and others that were distributed at a series of regional conferences for licensees'. This management decision included a provision that facilities licensed after this date would

be required to upgrade their QA Programs for operation to reflect new QA requirements developed by NRC as described in implementation sections of Regulatory Guides, etc.

D. REVIEW RESPONSIBILITY

1. <u>Initial Review and Approval of QA Plans</u>. NRR/QAB is responsible for the initial review and approval of the licensees QA Program description

(Docketed Program) which may be discussed in the SAR or in a Topical Report.

IE is responsible for reviewing those procedures (QA Manual) that are developed by the licensee to implement the QA Program description (Docketed Program).

- 2. Review and Approval of Changes to QA Plan. NRR/QAB is responsible for reviewing and approving changes to the Docketed QA Program. Currently, there is no Regulatory requirement for licensees to report such changes to NRR other than as required by 10 CFR 50.59. To help correct this situation, NRR is requesting licensees to modify their Docketed QA Program to include a commitment to submit changes to the approved QA Program for operation to NRR for review and approval prior to implementation of the change. With regard to Topical Reports, the current NRC letter to the licensee acknowledging acceptance of such reports includes language that requires submittal of subsequent changes to NRR.
- 3. <u>50.59 Review</u>. Proposed changes to the QA Program description in the FSAR or the Topical Report referenced in the FSAR must be reviewed by the licensee to ascertain whether the proposed change involves an unreviewed safety question as described in 10 CFR 50.59. The licensee must also maintain records of such reviews and document these changes in a report to the Commission as described in 10 CFR 50.59(b).

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